UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,010	02/02/2001	Gregory Bruce Wilson	0179/61248-A/JPW/BJA	7419

7590 01/11/2005

Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036

EXAMINER
LI, BAO Q

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/776,010	WILSON ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *32-40, 42-43 and 46-47*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-40,42,43,46 and 47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-40,42,43,46 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This is a response to the amendment, paper No. 19, filed 10/08/04. Claims 1-31, 41, 44, and 45 have been canceled. New claims 46 and 47 have been added. Claims 38-40 have been amended. Claims 32-40, 42, 43 and 46-47 are pending and considered before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 32-40, 42-43 and 46-47 are still rejected under 35 U.S.C. 103(a) on the same ground as stated in the previous Office Action, as being unpatentable over Wilson et al. (Patent No. 4,816, 563) and Ablashi et al. (Biotherapy, 1996, Vol. 9, pp. 81-86).

3. Applicants traverse the rejection and submit that Wilson and Ablashi in combination did not teach the invention in that neither Ablashi et al. nor Wilson et al. disclose an HHV-6A and/or HHV-6B specific transfer factor and a cell free fluid consisting essentially of mammary gland secretion from a mammary glad of a human herpesvirus-6 infected lactating mammal as claimed.

4. Applicants' argument has been fully considered; however, it is not found persuasive because Ablashi et al. teach a method for treating patients suffering Chronic Fatigue Syndrome (CFS) with antigen specific transfer factor (TF), which is active against EBV, HHV-6 and CMV. The TF is extracted from spleens of BALB/c mice immunized wit EBV, CMV, and HHV-6 live virus, in which the HHV-6 include HHV-6A and HHV-6B. While Ablashi et al. do not teach to use cell free product secreted from a mammal, Wilson et al. disclose a method for producing an antigen specific excreted transfer factor (TF) isolated from a colostrums or milk of a bovine, and

it can be lyophilized and stored dry for later use and/or reconstituted in sterile pyrogen-free water, physiologic saline or any other fluid suitable for injection or oral administration (lines 26 on col. 5 through line 68 on col. 6). Wilson et al. also teach that the antigen specific TF is used for enhance the cellular immunity against specific antigens to which the TF-producing animal is immunized, such as herpes simplex virus.

5. Therefore, it would have been obvious for a person skill in the art at the time the application was filed to be motivated by Ablashi et al and Wilson et al. to use the TF derived from the milk or clostridium product for treating the CFS because the TF derived from a mammal milk product for the convenient and economic reasons as stated in the previous Office Action. As the claimed invention is not claimed as an unexpected result, the rejection is still maintained.

6. Furthermore, Applicants point out that they do not understand which point the examiner is making regarding ejection is based whether the product disclosed in the prior art is the same product or obviousness of same product since in the last office action, the examiner cited that first, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Secondly, the effectiveness of using same product or obviousness of same product from 50% showed by the prior art vs. 90% effective of present application does not mean that the composition disclosed by the prior art is patentably different from the claimed composition.

7. In this context, because HHV-6 cited in the prior art more broadly include the all serotype HHV-6, the claimed composition comprising the HHV-6A or HHV-6B subtype specific transfer factor is an obviousness of same product of HHV-6 transfer factor. Unless, applicants point out that the HHV transfer factor specifically against serotype 6A or 6B can produced more significantly and unexpected result compared with the HHV-6 transfer factor.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 32-40, 42-43 and 46-47 are still rejected under 35 U.S.C. 102(b) as being anticipated by Advertisement by Chisolm Biological Laboratory in Positive Health News Report No. 17, Fall Issue 1998, p 29 in view of Advertisement by Chisolm Biological Laboratory in Positive Health News, Fall, 1997, p. 27.

10. Applicants traverse the rejection and submit that the product sold on the market by Chisolm is not same as the claimed product because there is inconsistent between the examiner's statement of the composition comprising the Transfer Factors formulated as a simple dried colostrums/whey products with the actual wording of the fall 1997 positive health news advertisement, which states that one should not be fooled by simple dried colostrums/whey products. Therefore, applicants asserted that there is no indication in the advertisement that the "Immunfactor" product is 'a free –fluid consisting essentially of a mammary glad secretion of a human herpesvirus-6A lactating animal". In fact, the advertisement suggests the "Immunfactor" is not clostrum-based. Accordingly, Applicants maintain that the cited reference does not teach all elements of applicants' claimed invention.

11. Regarding claim 40, applicants also argue that the cited references nowhere disclose or suggest a method for treating chronic fatigue syndrome comprising administering the mammary glad secretion from a HHV-6A and the mammary secretion from a HHV-6B immunized lactating mammal.

12. Applicants' argument has bee fully considered; however, it is not found persuasive because the massager delivered by the advertisement indicates that the ImmunFactor is a colostrums product, but it is not a simply dried colostrums/whey products that have already been sold in the market for years, such as a milk powder in the supermarket. It tells the consumer that the ImmunFactor is a particular colostrums product comprising an antigen specific transfer factor (TF) with an immunological stimulatory function. The concept of TF as a colostrums product is well accepted in the art, which is substantiated by the disclosure in the website provided in this office action. This website also teaches that Chisolm is the manufacturer, but the only place that sells the full range of Chisolm TF's (TF is a collection of messenger molecules normally passed in mammals from mother to child in colostrum — mother's milk during the first few days after birth. TF is a quick and effective way to "train"

the infant's immune system to recognize and react to the millions of pathogens to which the baby will soon be exposed. See website: http://www.users.on.net/~julian.robinson/cfs/tf.htm).

13. Moreover, the statement of report No. 16 of Positive Health News published in the Spring Issue 1998 clearly indicates that the ImmunFactor™ is used for treating chronic Fatigue Panel. The application of the ImmunFactor™ is used for treating chronic fatigue is also substantiated in the website of Chisolm. While, the website provided here is the up-dated one, it indicates that however, the ImmunFactor™ was first produced by the Chisolm company prior to the current application was filed and it is still in the sale market by the Chisolm company for treating chronic fatigue syndrome.

14. Considering the HHV-6 TF is a multivalent TF as disclosed by the Chisolm Company, it indicates that the composition comprising both HHV-6A and HHV6B TF and it is used form treating chronic fatigue syndrome. The new claims 46 and 47 are also anticipated by the cited Chisolm Company's product. Therefore, the rejection is maintained.

Conclusion

15. **No claims allowed.**

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li
1/08/2005

JAMES HOUSEL 1/10/05
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600